

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220



PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/003272

International filing date (day/month/year)
07.10.2004

Priority date (day/month/year)
08.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/00, A61K31/135

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Loher, F

Telephone No. +49 89 2399-7839



WRITTEN OPINION OF THE
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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,
 claims Nos. 28-30 (IA)

because:

the said international application, or the said claims Nos. 28-30 (IA) relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 no international search report has been established for the whole application or for said claims Nos.
 the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**WRITTEN OPINION OF THE
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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	4, 18-21
	No: Claims	1-3, 5-17, 22-30
Inventive step (IS)	Yes: Claims	
	No: Claims	1-30
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

IAP20 Rec'd PCT/PTO 06 APR 2006

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 28-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO 00/21521 A (PFIZER PRODUCTS INC; HARPER, NANCY, JANE; RANADE, GAUTAM, RAMCHANDRA;) 20 April 2000 (2000-04-20)

If not mentioned otherwise, the relevant passages are those mentioned in the International Search Report.

Art 33(2) The present application does not meet the requirements of Article 33(2) PCT, since the subject-matter of claims 1-3, 5-17 and 22-30 is not new.

D1 discloses a sertraline oral concentrate which is intended to be diluted in a suitable diluent or beverage. The concentrate contains sertraline hydrochloride, glycerine, ethanol, butylhydroxytoluene (BHT) and menthol. As the water content of glycerine is about 15% and a 95% ethanol is used in example 1 of D1, the water content of the composition disclosed in example 1 of D1 is about 13%. Therefore, the subject-matter of claims 1-3, 5-17 and 22-30 is not new in the light of D1.

Prior art does not describe the manufacture of a composition wherein 10-25% water has been added or the composition is filtrated after water has been

added..

Art 33(3) The present application does not meet the requirements of Article 33(3) PCT, since the subject-matter of claims 1-30 does not seem to involve an inventive step.

D1, which is considered to represent the most relevant state of the art, discloses a concentrate which contains sertraline hydrochloride, glycerine, ethanol, butylhydroxytoluene (BHT) and menthol. This oral concentrate is intended to be diluted in a suitable diluent (water) or beverage (orange juice, ginger ale, lemon-lime soda, lemonade, sugared tap water, cranberry juice, grapefruit juice, tomato juice, pineapple juice, prune juice...) prior to administration.

The problem to be solved by the present invention may therefore be regarded as how to provide an improved galenical formulation of sertraline.

The present application suggests to solve the problem posed by providing a pharmaceutical (oral liquid) composition which comprises sertraline (hydrochloride) and water in an amount between >10% up to 40%. The composition further comprises hydrochloride, glycerine, ethanol and butylhydroxytoluene (BHT).

Taking into account the teaching of the cited prior art the following reasoning applies:

With respect to the subject-matter of claims 1-3, 5-17 and 22-30 the applicant's attention is drawn to the fact that even if novelty could be established over the above-cited prior art it is at present not clear wherein an inventive step may reside.

With respect to the subject-matter of claims 4 and 18-21 the applicant's attention is drawn to the fact that there seems to be no basis for inventive step within the present application as filed since no evidence can be found that the features which are novel result in a solution of the posed problem which could not have been foreseen by the skilled person.

Being aware of the teaching of D1 the skilled person simply performed the steps (adding water) that were suggested by D1.

As there is no surprising effect resulting therefrom, the solution proposed in

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claims 4 and 18-21 of the present application is not considered to be inventive in the sense of Article 33(3) PCT.

It is therefore noted, that the solution proposed in claims of the present application is not considered to be inventive in the sense of Article 33(3) PCT.

Art 33(4) For the assessment of the present claims 28-30 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

The subject-matter of claims 1-27 is considered to be industrially applicable in the sense of Art 33(4) PCT.